Cell Stem Cell
Forum

A Legal Defense for Compensating Research Egg Donors

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Given the continued need for human eggs for hESCs, this article analyzes and refutes the legal theories against compensating research egg donors, contrasts the legal histories of compensating reproductive donors and human subjects with noncompensation for ESC donors, and suggests that limited compensation is legally defensible.

With a change of administrations in the United States and renewed support for human embryonic stem cell (hESC) research, there may be an opportunity to reassess the legal principles and theories involved in payments to research egg donors in this country and to consider how the legal system might impact this ongoing debate. In this rapidly moving field, many observers and some researchers have argued that developments in both adult stem cell research and more recently induced pluripotent stem cell (iPSC) research should obviate the need for donated research eggs. However, adult stem cells have already-recognized limitations and the jury is still very much out as to whether iPSCs will ever replace hESCs in terms of clinical potential. Moreover, each of these research paths carries the potential of enhancing advances in the other areas and in understanding early human development, indicating that there is a continued need for donated research eggs (Cibelli, 2009). Anecdotally, the present dearth in research egg donors has been repeatedly traced to an inability to compensate them. One recent study of reproductive donors found that most of these individuals were interested in donating for embryonic research, but only 2% were willing to do so without compensation (Klitzman and Sauer, 2009). Although the legal issues should be of worldwide interest, given the range of international laws and policies, this article is limited to a discussion of compensating research egg donors within the United States. It reviews both the legal background in the United States and various legal arguments that have been made regarding compensation for egg donation and then suggests the viability of a legal defense for modest compensation to research egg donors under the same protections and principles applied to other human research subjects.

With few exceptions (such as the 2009 decision by New York state's Empire State Stem Cell Board to allow research donor compensation), current compensation practices for research egg donors stand in stark contrast to such policies for both healthy human research subjects and reproductive egg donors. Policies prohibiting donor payments or permitting research use of only "spare" IVF embryos have been incorporated into otherwise pro-hESC research legislation and voluntary restrictions by professional organizations. These restrictions codify into law or guidelines ideological perspectives that may lack objectivity, scientific acumen, or the flexibility needed to adapt to anticipated advances in this fast emerging and promising field. From a legal perspective, the discussion should be about how best to protect these healthy human subjects through established protocols, rather than how to appease opponents of hESC research through restrictive statutory provisions.

The Law and Legal Theories

Generally speaking, the law attempts to shape behavior both prospectively by enacting statutes and guidelines and creating entities such as licensing bodies to address certain behaviors set out by those acts and by making courts available to individuals and the government to redress actions that allegedly offend those laws or existing theories of constitutional, criminal, tort, or contract law. Both approaches are relevant in the arena of payments to research egg donors, and any legal defense of compensating research egg donors must recognize the existing paradigms and theories that currently impact this issue.

Opponents of compensating research egg donors suggest that paying these women is coercive, unduly influences poor or otherwise vulnerable women to put themselves at risk, and commodifies eggs and that it is simply wrong to "create life to destroy it." However, none of these arguments withstand careful legal scrutiny.

Coercion

Legally speaking, coercion occurs when forces are exerted upon an individual such that his or her free will is removed, and any subsequent actions are considered to be involuntary. A common legal example is holding a gun to someone's head to force them to act in a way they would not otherwise. Regardless of how one feels about compensating research egg donors, it does not follow that modest proposed financial compensation would remove a potential egg donor's free will. In fact, given that Hwang lab members have alleged that professional pressures induced them to donate oocytes for their employer's studies, coercion (and undue influence) is more likely a result of such pressure on would-be donors than large sums of money (Chong and Normile, 2006). Compensation for human subjects, including men, women, and children, is a commonly accepted principle, accompanied by established protections and approved protocols. Only in response to potential donations involving women's reproductive potential are such calls of coercion voiced and frequently prevail (Vogel, 2006). To suggest that paying

research egg donors is coercive would call into question the voluntariness and free will of virtually every compensated reproductive egg donor as well as every healthy human research subject.

Undue Influence

"Undue influence" is the more accurate legal construct to argue against compensating egg donors. In contrast to "coercion," undue influence is a legal theory that in some circumstances, an inducement is so substantial, or the person offering it is in such a position of relative power, that it unfairly impacts or influences a person's actions. (Hyun, 2006). Such concerns have been raised in the United States over offering an infertility patient who cannot afford treatment a free or discounted IVF cycle if she agrees to split her eggs with another patient, essentially making her both a donor and a recipient.

The various compensation amounts proposed for research egg donors are a fraction of that paid to reproductive egg donors: some of the larger suggested amounts have been $1,000 to $1,500, compared to an accepted range of $5,000–$10,000 for reproductive donors (see Ethics Committee of the American Society of Reproductive Medicine [ASRM], 2007). On one hand, it seems unlikely that a prospective research donor who also had an option to donate for reproduction would be unduly influenced by the relatively small sum that researchers would offer. On the other hand, some potential research donors may not be eligible to serve as reproductive donors because of their education, health, or socioeconomic strata and thereby be arguably more susceptible to lower remuneration offered them as a research donor. The opposite argument may also apply, given that older women with established families and lifestyles may also be interested in research donation, but less susceptible to financial inducements than young reproductive donors. The question of determining what is and isn't undue influence suggests the need for clear, sensitive, factually based and appropriate compensation guidelines reflecting compensation for a donor's time, effort, risk, and inconvenience and not for the eggs themselves.

Commodification

Another frequently voiced argument is that paying egg donors reduces their eggs to commodities. However, many research donors are paid for their time and discomfort. In these cases, following rigorous IRB protocol and safeguards allows modest remuneration that reflects approximate and reasonable compensation for the time, effort, inconvenience, and risk undertaken by these healthy research subjects, as opposed to payment for their donated tissue. The ISSCR supports such an approach in the case of research oocyte donation by approving compensation provided that appropriate rates are determined by individual jurisdictions. At their core, commodification concerns are an argument against exceedingly and unjustifiably high payments, an issue rooted in the existing context of reproductive donation in which compensation guidelines are at times only loosely followed. Given that hESC research doesn't care about a donor's SAT scores, athletic prowess, or hair or eye color, setting appropriate compensation amounts for research donors may actually help model more appropriate compensation guidelines for reproductive donors.

Procreation versus Research

A final, largely ethical argument put forth by opponents is that donation for procreation is a greater good because it helps create life, which justifies existing discrepant payment paradigms. Yet, a survey of reproductive egg donors revealed that they were evenly split in their preference for research or reproductive donations (Klitzman and Sauer, 2009). Undoubtedly, some donors, ethicists, and policy makers have stronger feelings about either procreation or research, but in a pluralistic society those individuals' values should not be adopted into law.

A Brief Legal History of IVF, Egg Donation, and Fetal Research

Considering the histories of compensating reproductive donors and the legal restrictions on embryonic research in the United States may aid in forging future laws and policies. Both egg donation and ESC research became possible only after IVF created the novel ability to create ex utero embryos some 30 years ago. Both have evolved in the large shadow of a national abortion debate fueled by the Supreme Court's decision in *Roe v. Wade* (1973).

Over the past two decades, reproductive egg donation has evolved from an informal, empathetic response by relatives and friends into an industry comparable to sperm donation, but with added medications, procedures, and attendant risks and significantly greater remuneration. Egg freezing, although still considered experimental, is increasingly available and promoted and will probably transform the field further in terms of medical protocols, remuneration, and providing potentially "spare" eggs for future research donation. It is also important to recognize that, in terms of known safety risks, the technology and medical risks associated with egg stimulation and retrieval have been undertaken by IVF patients since the early 1980s.

Reproductive donors are currently recruited by patients, ART medical programs, and separate recruiting programs, over the Internet, and elsewhere. In contrast to research donors (and laws in other countries), compensation for reproductive egg donors is accepted practice in the United States with no federal laws prohibiting such payments. A federal and model uniform law that each regulate and restrict compensation for organ donations do not encompass egg donations from live donors. The Uniform Anatomical Gift Act (UAGA, 1968) restricts payments for body parts that are removed after the death of the donor, whereas the National Organ Transplant Act (NOTA, 1984) prohibits "valuable consideration" for a list of defined "organs" and expressly denies payment for related expenses such as travel and lost wages. NOTA's criminal penalties are primarily aimed at preventing the sale of nonrenewable solid organs, including kidneys, livers, hearts, and eyes, which could compromise a donor's health and well-being. Ironically, bone marrow is explicitly included as an "organ" although it is renewable in a matter of weeks, whereas eggs are not included. (Although eggs are nonrenewable, many analogize them to renewable tissue such as blood and sperm on the theory that females are born with many more eggs than they can ever use in their lifetime). The first lawsuit to challenge the constitutionality of NOTA was filed by Doreen Flynn, a mother of three children who could benefit from bone marrow transplants (*Flynn v. Holder*, 2009). Flynn argues the

law is unconstitutional and violates both equal protection and substantive due process rights by arbitrarily treating renewable bone marrow like nonrenewable solid organs, rather than like blood—or, ironically, eggs. The government must only prove a rational basis, the lowest legal standard to pass constitutional muster, but regardless of the ultimate outcome, the issues raised by the case could impact debate over compensating research egg donors, as well.

In the absence of legal restrictions on compensation within the United States, payments to reproductive donors are limited only by general tort law or professional guidelines. Voluntary guidelines and ethics statements issued by ASRM permit per-cycle payments for donors of approximately $5,000, and up to $10,000 (Practice Committee of the ASRM, 2006), and have recently required any recruiting program listed on its Web site (at last count over 80) to agree to adhere to those principals. Although frequently self-described as "agencies," these entities are widely unregulated. ASRM guidelines also state that compensation is for a woman's "time, inconvenience and discomfort" in undergoing the rigors of donation, not for the eggs themselves or for any specific donor qualities (Practice Committee of the ASRM, 2006; Ethics Committee of the ASRM, 2007). Nonetheless, some reproductive donors receive tens of thousands of dollars from both individuals and recruiting programs, as well as additional fees for a desired ethnicity or proven fertility.

The legal history of fetal and embryonic research is quite different. In the immediate wake of *Roe v. Wade*, many states enacted legislation to prohibit fetal tampering or fetal "experimentation" and defined the term "fetus" to include "embryo." A number of those laws were unclear and overbroad, and in 1990, the ACLU joined a group of Illinois doctors who successfully sued to have that state's statute voided for vagueness, arguing they could not tell what forms of research were or were not permissible (*Lifchez v. Hartigan*, 1990). The Massachusetts statute, enacted in 1974, required research be approved by the district attorney and provided criminal penalties, including incarceration, for anyone conducting any form of experimentation using a live fetus, embryo, or neonate. In 1975, Dr. Kenneth Edelin, then the chief resident in obstetrics and gynecology at Boston Medical Center, was convicted for performing a second-trimester abortion after a nurse reported he held the fetus's head in the uterus longer than necessary. The jury's manslaughter conviction was subsequently overturned on appeal (*Commonwealth v. Edelin*, 1976), but the case is a searing reminder of both the intensity of emotion *Roe v. Wade* ignited and the willingness of some to use the legal arena against an individual to advance an ideological agenda. Although almost a decade would pass before IVF and cryopreservation made research on ex utero embryos possible, many of those laws and the antiabortion sentiments behind them are still in force and impacting current debates over ESC research (Crockin and Jones, 2010).

Current Embryo Research Legislation

Thirty years later, the advent and potential of ESC research has renewed legislative and policy efforts to advance science while appeasing both religious opponents and some elements of feminist opposition. As with 1970s era legislation, results have been mixed. In Massachusetts, following decades of researchers' concerns that their work might run afoul of the existing statute, new legislation was enacted in 2005, after lengthy hearings (Massachusetts General Laws, 2005). Numerous physicians, researchers, and other experts testified, giving detailed explanations of the science, technology, hope, and limitations of hESC research. Many senators noted it was the most educational experience of their legislative careers. It was a compelling example of scientists managing to influence law and policy. In the final days of the hearings, however, opponents testified about potential negative health impacts of the procedures and warned that compensation might make poor, minority women risk their health to donate eggs. Provisions inserted into the final legislation ban payments or "valuable consideration" to research donors and mandate that two documents be provided to any woman undergoing egg retrieval: a detailed "informational pamphlet" describing the potential health impacts of the egg extraction process and a mandatory "informed consent form." A deep internal inconsistency also appeared in the final legislation, with a different section of the statute stating that the law was not intended to regulate reproductive IVF. With hESC research proponents getting most of what they fought for, the law passed to much acclaim. Researchers have since found the law's compensation prohibitions have severely impacted their ability to attract egg donors for their research.

California's 2004 stem cell law contains a similar payment prohibition for research egg donors. A 2008 Michigan law supporting hESC research authorizes use of only leftover IVF embryos for approved research. Professional groups are split. Voluntary guidelines issued by the International Society for Stem Cell Research endorse local IRB decision making over compensation. Last year, New York approved compensation for research donors in that state. In contrast, the National Academy of Sciences continues to endorse only extremely limited reimbursement for direct expenses, although in 2007–2008, it slightly relaxed its strict payment moratorium to allow some out-of-pocket reimbursement. ASRM has criticized that position and supports compensation for research donors (Ethics Committee of the ASRM, 2007).

These compromise statutes and policies fail to recognize that compensating healthy human research subjects (including children and other "vulnerable subjects" with additional safeguards) is an accepted, long-standing, and legally recognized practice in medical research. Rationales for compensation include incentives to recruitment, overcoming disincentives such as inertia and distrust, reimbursement to reduce financial barriers to participation, and fair compensation for subjects' time and inconvenience (Grady, 2005). The primary arguments against such payments have focused on ethical—not legal—concerns, whether compensation undercuts altruism, and the extent to which compensation may threaten voluntary, informed consent (Hutt, 2003). Safeguards, including federal and state laws and IRB approval, require a careful analysis and weighing of risks and benefits.

Moving Forward from a Legal Perspective

Human research subjects have been paid for over a century, within frameworks

that are designed to minimize undue influence on informed consent. Reproductive sperm and egg donors are routinely compensated to help create children. Yet, compensating research egg donors has become a virtual "third rail" in the shaping of ESC research policy. Given these two established paradigms, the impassioned resistance and resulting compromise laws and policies are difficult to justify. Rather than an ideologically based debate, from a legal perspective, laws and policies can be crafted that address the potential danger of undue influence and commodification while incorporating both protections and compensation for healthy human research subjects under long-established, if imperfect, methods. Attempts to satisfy the ethical objections of hESC research opponents should not result in either disparate treatment for reproductive versus research egg donors or turning solely to research on adult stem cells or iPSCs that cannot replace the need for hESC research. Notably, efforts that combine all avenues of stem cell research may, in time, reduce the number of eggs ultimately sought or needed for stem cell research (Cibelli, 2009).

In this burgeoning field, researchers continually remind us not to put all our proverbial eggs in one basket by endorsing only iPSC or adult stem cell research. In no other field involving human research subjects are promising avenues of inquiry cut off for purely ideological reasons, whether through well-meaning but problem-riddled legislation or well-intended but politically compromised voluntary guidelines. From a legal perspective, there is no justification to deny researchers or those women who want to be human subjects the opportunity to move this promising science forward under the same ethical, legal, and policy paradigms that apply to every other area of scientific inquiry. To force researchers, potential human subjects, legislatures, and society at large to reject compensation either because of the religious or ideological views of one segment of the population or the notion that female research subjects uniquely need more protections in this arena than in any other—now *that* would be coercive.

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